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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,500	12/05/2005	Takashi Suzuki	OKA-0230	1582
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Cheng Law Group, PLLC 1100 17th Street, N.W. Suite 503 Washington, DC 20036				
EXAMINER				
NGUYEN, QUANG				
ART UNIT		PAPER NUMBER		
1633				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/559,500

Applicant(s)

SUZUKI ET AL.

Examiner

QUANG NGUYEN, Ph.D.

Art Unit

1633

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 10-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date 10/8/08
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This application was transferred to Examiner Quang Nguyen, Ph.D. in AU 1633.

Applicant's amendment filed on 10/02/08 was entered.

Amended claims 1-13 and new claim 14 are pending in the present application.

This application contains claims 10-13 drawn to an invention nonelected without traverse in the reply filed on 12/28/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim 6 was also withdrawn previously because it is directed to a non-elected species.

Accordingly, amended claims 1-5, 7-9 and new claim 14 are examined on the merits herein with the elected species of "a cell derived from a gonad".

Information Disclosure Statement

All of the documents submitted in the IDS dated were considered by the examiner. However, the Notification of reasons for refusal for the Application No. 2005-506975 is not a proper reference, and therefore it was crossed out.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended claims 1-5 and 7-8 are still rejected under 35 U.S.C. 102(b) as being anticipated by Elliott et al (US 5,716,985) for the same reasons already set forth in the Office Action mailed on 6/02/08 (page 3). ***The same rejection is restated below.***

Elliott et al. teaches a method comprising suspending CHO cells in a buffer containing protease inhibitors, centrifuging the cells, rapidly freezing the cells in liquid nitrogen, thawing the cells on ice and centrifuging the lysate (See especially the second full paragraph in column 11). The method of Elliott et al. comprises all of the elements of the instant claims and produces a mammalian cell extract liquid. Therefore, the claims are anticipated by Elliott et al.

Response to Arguments

Applicants' arguments related to the above rejection in the Amendment filed on 10/02/08 (pages 4-5) have been fully considered but they are respectfully not found persuasive for the reasons discussed below.

Applicants argue basically that the Elliott et al reference does not teach or suggest the limitation "for cell-free protein synthesis", and therefore the reference does not teach all the limitations of the claims. Applicants also argue that Elliott et al only teach a CHO cell membrane preparation for a binding assay which is completely unrelated to the cultured mammalian cell extract for cell-free protein synthesis.

Please note that the limitation "for cell-free protein synthesis" in the preamble of currently amended claims simply indicates the intended use for a cultured mammalian cell extract. The method of Elliott et al is still indistinguishable from the presently claimed method because it still has the same method step(s) and starting material(s) (e.g., cultured mammalian cells and an extraction or lysis solution), even though the CHO lysate of Elliott et al was prepared for a purpose other than for cell-free protein synthesis.

Accordingly, Elliott et al still anticipate the instant claims as broadly written.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claim 9 is still rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott et al (supra), as applied to claim 8 herein above, in view of Reiter et al. (US 6,475,725) for the same reasons already set forth in the Office action mailed on 6/2/08 (pages 3-5).

Response to Arguments

Applicants' arguments related to the above rejection in the Amendment filed on 10/02/08 (pages 4-5) have been fully considered but they are respectfully not found persuasive for the reasons discussed below.

Once again, Applicants argue basically that the both the Elliott et al reference and Reiter et al reference do not teach or suggest the limitation "for cell-free protein synthesis", and therefore the references do not teach all the limitations of the claims. Applicants also argue that Elliott et al only teach a CHO cell membrane preparation for a binding assay which is completely unrelated to the cultured mammalian cell extract for cell-free protein synthesis.

Please note that the limitation "for cell-free protein synthesis" in the preamble of currently amended claims simply indicates the intended use for a cultured mammalian cell extract. The modified method resulting from the combined teachings of Elliott et al and Reiter et al. is still indistinguishable from the method in claim 9 because it still has the same method step(s) and starting material(s) (e.g., CHO derived from CHO K1-SFM and an extraction or lysis solution), even

though the cell lysate resulting from the combined teachings is intended for a purpose other than for cell-free protein synthesis.

Accordingly, amended claim 9 is still rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott et al (supra), as applied to claim 8 herein above, in view of Reiter et al. (US 6,475,725) for the same reasons already set forth in the Office action mailed on 6/2/08 (pages 3-5).

New claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott et al (US 5,716,985) in view of either Shay et al (US 6,210,915) or Brewer, G (US 5,543,499). ***This is a new ground of rejection necessitated by Applicant's amendment.***

Elliott et al. teaches a method comprising suspending CHO cells in a buffer containing protease inhibitors, centrifuging the cells, rapidly freezing the cells in liquid nitrogen, thawing the cells on ice, homogenizing in lysis buffer containing 20 mM Tris HCL (pH 7.5) and the protease inhibitor cocktail and centrifuging the lysate (See especially the second full paragraph in column 11).

Elliott et al do not teach specifically lysing the CHO cells in an extraction solution or lysis solution containing at least a potassium salt, a magnesium salt, dithiothreitol and a buffer.

At the effective filing date of the present application, Shay et al already taught the use of a cell lysis buffer containing at least protease inhibitors, dithiothreitol, buffered ions (Tris, Hepes) and salts such as magnesium chloride and potassium chloride and

others for extracting telomerase from a cell sample, including from a mammalian cell sample (see at least Summary of the Invention; particularly, col. 4, lines 49-62; col. 5, lines 57-65).

Brewer also disclosed at least the use of a lysis buffer containing Tris-HCl, magnesium acetate, potassium acetate, dithiothreitol and protease inhibitors for extracting the tumor suppressor gene product AUF1 from human mammalian cells (see at least col. 13, lines 9-17).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the cell lysis buffer taught by Shay et al or Brewer in the method taught by Elliott et al. In *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), the Supreme Court particularly emphasized "the need for caution in granting a patent based on a combination of elements found in the prior art," (*Id.* At 1395) and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." (*Id.* At 1395.).

In the instant case, the method of Elliott et al. differs from the method presently claimed in new claim 14 in the solution for extraction comprising specifically at least a potassium salt, a magnesium salt, dithiothreitol and a buffer. However, the teachings of either Shay et al or Brewer already demonstrated that a mammalian cell extraction or lysis solution contains these specifically recited components was known and used in the art at the time of invention. One of ordinary skill in the art could have substitute anyone

of the cell lysis buffer taught by either Shay et al or Brewer in the method of Elliot et al with the predictable outcome for preparing CHO cell lysate.

In view of the foregoing, the method of new claim 14, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore, the claim is properly rejected under 35 U.S.C. 103(a) as obvious over the art.

Conclusions

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/QUANG NGUYEN/

Primary Examiner, Art Unit 1633